

REMARKS

Applicant respectfully submits this amendment pursuant to 37 C.F.R. §1.116 in response to the Final Office Action of November 9, 2009. Claims 44-52 are pending in the application. In the current Office Action, Claims 44-52 stand rejected under 35 U.S.C. §103 as being unpatentable over Carter, U.S. Patent No. 6,478,791 in view of Geitz, U.S. Patent No. 6,592,596. In Applicant's most recent amendment, an issue was raised as to whether a *prima facie* case of obviousness had been established. The Final Office Action did not address the issue, leaving Applicant unaware of the Office's position. In order to more squarely present the issues for appeal, it is necessary to fully understand the Office's position. Accordingly, Applicant respectfully requests that this amendment be entered and that reconsideration be given or a response entered on the merits of Applicants grounds for patentability.

Rejection of Claim 44 Under 35 U.S.C. §103

Claims 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,478,791 ("Carter") in view of U.S. Patent No. 6,592,596 ("Geitz"). Carter is directed to the provision of therapy for incontinence by selectively reducing an effective length of the endopelvic fascia or other endopelvic support tissues. [Carter, Col. 5, lines 22-25].

"this effective shortening of the endopelvic fascia, together with any stiffening of the fascial structure (through the formation of adhesions, the application of heat or radio frequency potential, or the like) will be sufficient to improve the support of the urethra, bladder neck, and bladder so that incontinence is inhibited." [Col. 7, l. 63 – Col. 8, l. 2]

The endopelvic fascia, which is shortened in the procedure outlined by Carter, is described as by Carter as follows:

"Of particular importance for the method of the present invention, endopelvic fascia EF defines a hammock-like structure which extends between the left and right arcus tendinous fascia pelvis ATPF. These latter structures extend substantially between the anterior and posterior portions of the pelvis, so that the endopelvic fascia EF largely defines the pelvic floor." [Col. 5, lines 53 – 59]

Carter depicts the endopelvic fascia in Figure 15a, reproduced here:

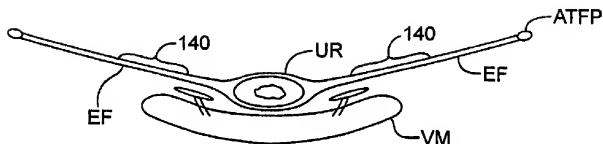


FIG. 15A

As one can see, the endopelvic fascia, **EF**, referred to by Carter as a "hammock-like structure," is a thin tissue stretched between the left and right arcus tendinous fascia pelvis **ATFP**.

Claim 44 is a method claim reciting a series of steps. The Claim is reproduced here for convenience.

44. A method of acquiring tissue from within a hollow body organ, comprising:
 positioning a first acquisition member and a second acquisition member adjacent to a region of tissue within the hollow body organ, wherein the first and second acquisition members are in apposition to one another along a first longitudinal axis in an open configuration;

adhering tissue from the region within each of the first and second acquisition members; and

compressing the adhered tissue between the first and second acquisition members in a closed configuration.

In the previous Office Action, it was asserted that Carter teaches the foregoing steps of Claim 44, citing to Figure 9A and 9B of Carter. The Office Action contended that the first and second acquisition members correspond to arms 52, and that the steps of "adhering tissue from the region within each of the first and second acquisition members" and "compressing the adhered tissue between the first and second acquisition members" are taught by Figure 9. Applicant respectfully disagreed. The discussion of Figure 9 is set forth in two paragraphs of column 8 of Carter, lines 35 – 51. Carter first states that the arms 52 have roughened surfaces 36 to engage and draw the fascia surface inward. As the tissue is moved inward, the fold retainers 54 push the tissue away from the arms into a fold 22. The arms 52 act in the same manner as the rollers 36 of Figure 8, gripping the surface of the tissue but not "adhering tissue . . . within each of the first and second acquisition members" and not "compressing the adhered tissue."

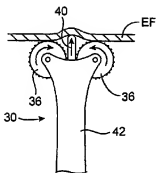


FIG. 8B

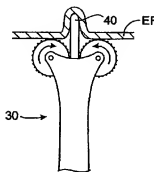


FIG. 8C

Applicant pointed out that Claim 44 requires that the adhered tissue **within each** of the first and second acquisition members. If the Office Action contends that the arms "grip" the fascia in a manner similar to the wheels shown above, then Applicant questioned how the claim limitation is met that tissue is adhered **within each** acquisition member. The arms are solid structures that do not have any cavities or recesses for which tissue could be adhered **within**, and Applicant pointed this out in prior amendment.

As Applicant stated, there is nothing in the Carter disclosure that establishes the region of tissue occurs "within" the acquisition members, since the surface 36 that grips the fascia in Carter is on the outside of the arm. Moreover, the rod 54 pushes the tissue away from the arms 52 to ensure that the material does not fold between the arms. Applicant specifically requested clarification on this issue, stating:

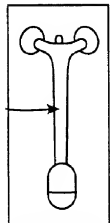
"If the Office Action contends that any of these limitations are still met by the Carter reference, Applicant respectfully requests that a non-final office action be issued explaining:

a) where Carter teaches that the endopelvic fascia tissue is "adher[ed] . . . within each of the first and second" arms 52; (Applicant contends it is designed and teaches that the tissue is folded away from the arms)"

The Final Office Action's "Response To Arguments" section is silent as to the issue raised, or simply contends that Carter teaches the step without explaining how. Applicant is left to speculate as the Examiner's position, making the appeal process inefficient and contrary to the regulations set forth in the MPEP. Accordingly, this Rule 116 Amendment is properly entered and Applicant respectfully requests reconsideration.

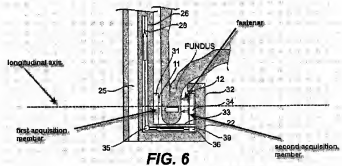
Applicant would further like to address the Office Action's handling of the motivation to combine the Carter and Geitz references. Applicant respectfully pointed out the purported inconsistencies that would make the proposed combination non-obvious. In response, the Office Action did not address Applicant's remarks but merely concluded that since both references are to medical devices, it would have been obvious to combine the references. This is not a proper rejection under §103.

Carter's device is a linear device as shown right. Since it is inserted directed through an incision, there is no change of direction required or contemplated. Conversely, Geitz must handle the problem of



being inserted down the esophagus and then applying a tissue fold beyond the gastroesophageal junction. It has a cup-shaped configuration to overcome the problem of how to fold tissue that is not in line with the path of travel of the device.

The Office Action contends that "the device of Carter can be used to secure different types of tissues, including the ones taught by Geitz." [Office Action, p. 6]. This is not the standard for obviousness, however. Nor is the standard whether the Office Action can use the Applicant's disclosure as a template for piecing together various prior art to match the claimed invention. Rather, the Office Action must show or explain, with evidence of record, why a person of ordinary skill in the art, armed with the Geitz and Carter references, would have found it obvious to combine them. Applicant respectfully submits that a linear tool like Carter would never be considered, much less found obvious, for securing tissue in Geitz. For one thing, the Office Action does not explain how the change in direction would be accomplished. That is, how could Carter's linear tool be passed down the esophagus like Geitz (see below) and then change direction 180° and acquire tissue at the bottom of the esophagus while operating in the same manner as Carter teaches? The simple answer is it cannot, because it is designed for a direct, linear approach. There is no advantage, and significant disadvantages, to the proposed combination which negates any suggestion that the combination is obvious. Applicant respectfully submits that a proposed combination of references must be examined for what they teach and what they do before they are blindly combined under the logic that they are both medical devices.



The Supreme Court in KSR International v. Teleflex Inc., which is cited by the Office Action, cautioned against the use of hindsight and analysis that is tailored from the Applicant's disclosure: "A factfinder should be aware, or course, of the distortion caused

by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." The Office Action appears to be guilty of this very tactic, where two wholly disparate teachings are combined with no rational or proper basis for utilizing the tools of one to solve the problems of the other, other than that it has been held that "use of a known technique (creating fold within a hollow body organ) to improve similar devices (fold for creating devices) will yield predictable results." O.A., p. 4

Conclusion

The combination of Carter and Geitz fails to teach all of the claim limitations of Claim 44, and there suggestion to combine the references is the product of impermissible hindsight. There is no analysis to support the purported combination, merely the platitude that known techniques are interchangeable. When the actual devices and techniques are scrutinized, however, there is no rational or logical reason that one of ordinary skill in the art would apply one teaching to the other, for the tools are used for different purposes and different tasks. Accordingly, the proposed combination is properly withdrawn. There are no outstanding valid rejections of pending Claim 44, and therefore Applicant respectfully submits that the claim is in condition for allowance. The allowance of Claim 44 renders the remaining dependent claims allowable, and early notification of same is requested.

If the Examiner believes that a telephone conference will further the prosecution of this application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is authorized to charge any deficiencies or fees in connection with this amendment to Deposit Account No. 06-2425.

Respectfully submitted,
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